

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Reed GAMBLE  
Serial No.: 10/573,247  
Filed: March 23, 2006  
For: PATCH FOR REDUCING EXPOSURE OF SKIN TO ULTRAVIOLET RADIATION

Group Art Unit: 1616  
Examiner: KARPINSKI, Luke E  
Confirmation No. 3023

Commissioner for Patents  
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**DECLARATION OF PROFESSOR SIR ALEXANDER MARKHAM  
UNDER 37 CFR §1.132**

I, Professor Sir Alexander Markham, of The Leeds Institute of Molecular Medicine, University of Leeds, St James's University Hospital, Leeds LS9 7TF, United Kingdom and ex-Chief Executive Officer of Cancer Research UK, do hereby declare and say as follows say as follows:

1. I am the author or co-author of more than 300 scientific publications and am a named inventor on more than 30 patent applications. I attach hereto my CV.
2. I have read US Patent Application No 10/573,247 ("the Application"). I have also read the official communication dated 16 December 2010 issued by the USPTO in connection with the Application and am aware of the documents cited therein, specifically Muchin et al and Edwards et al.
3. There are many conditions of, or affecting, the human skin. The skin normally and frequently displays pigmented and non-pigmented lesions such as moles, freckles, skin tags, benign lentigines, and seborrheic keratoses. The most common pre-cancerous skin conditions are actinic keratosis and dysplastic nevus (atypical mole).
4. Some lesions can progress to malignant growths and the only truly effective way for an individual to ensure that any "suspect" lesion is non-harmful or potentially non-cancerous is a biopsy and pathological assessment.

5. It is a well known fact that sunlight, if not a primary factor, is at least a contributory factor in the causation and progression of metastatic malignant melanomas. It is also a fact that the majority of primary skin neoplasms occur in skin that is, or has been, exposed to adverse conditions. World melanoma incidence rates reflect the high risk for white populations in sunny climates with Australia and New Zealand leading the world with age-standardized rates of between 30-40 per 100,000 population and North America coming second at between 12-20 per 100,000 population.
6. The invention claimed in the Application is a transparent patch that is opaque to both UVA and UVB light, a method of manufacturing the patch, a method of reducing skin exposure to UV radiation involving applying the patch to skin and the above when patch applied to the skin. The patch is intended to prevent any penetration of sunlight to a particular area of skin beneath the patch, for example a dysplastic nevus whilst allowing visualization of the covered area.
7. Muchin et al discloses a dermatological patch for removing keratotic plugs. The patch is placed temporarily over the offending keratotic plug and stripped away so pulling the keratotic plug or blackhead out whilst leaving it sticking to the adhesive composition provided on the patch. Even if the patch of Muchin et al were provided with a UVA or UVB blocking agent which the Examiner seems to be suggesting is the purpose of zinc oxide, I seriously doubt whether this would have any effect on the prevention of UVA and UVB light exposure to the skin underneath as firstly, the patch is put on temporarily merely to remove the blackhead and would be conducted in the privacy of one's home (an environment typically not associated with high UVA and UVB levels). A skilled man in the art or a clinician looking to prevent UVA and UVB penetration to a mole or the like would simply not look at this document for any guidance. The patch of Muchin et al is for cosmetic or beautifying purposes whereas the patch of the claimed invention has a genuine clinical and preventative purpose. The patch of Muchin et al, in removing the keratotic plug, would also lead to the removal of surface dermal cells around the keratotic plug. It would not be desirable to cause any unnecessary abrasion or to actively remove surface dermal cells from either the mole itself or for example an area of actinic keratosis. Muchin et

In re: Reed GAMBLE

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Page 3 of 3

al is simply not a serious starting point for the skilled man to develop the present claimed invention.

8. Turning to Edwards et al, this relates to fabrics such as nylons, acrylics, acetates, polyesters, Dacron, Lycra, Spandex, cotton, rayon, wool, silk, polyethylene and polypropylene [column 2 lines 31-33] to form articles such as clothing, awnings, umbrellas, sunscreens, tents, tarps and canvases [column 2 lines 17-19]. In my opinion, it is completely unrealistic that Edwards et al provides any incentive towards a transparent patch. A skilled man in the art would simply not contemplate this document in the context of providing a transparent patch in a clinical setting.
9. A combination of Muchin et al with Edwards et al is simply not plausible to result in the claimed invention of the Application. In conclusion it is my considered opinion that the present claimed invention is not obvious in view of Muchin et al over Edwards.
10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Professor Sir Alexander Markham



Date